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Draft Guidance on Avanafil

October 2024

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Active Ingredient: Avanafil

Dosage Form: Tablet

Route: Oral

Strengths: 50 mg, 100 mg, 200 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 200 mg
   Subjects: Healthy males
   Additional comments: Coadministration of avanafil with any form of organic nitrate is contraindicated due to the potentiation of hypotension. Nitrates should not be administered to subjects for at least 12 hours after the last dose of avanafil and should be administered under close medical supervision with appropriate hemodynamic monitoring.

Analyte to measure: Avanafil in plasma

Bioequivalence based on (90% CI): Avanafil

Waiver request of in vivo testing: 50 mg and 100 mg strengths based on (i) acceptable bioequivalence study on the 200 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*